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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/619,548

07/16/2003

Robert Flower

14398

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21127

7590

04/24/2006

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BOSTON, MA 02109

EXAMINER

JOHNSON III, HENRY M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/619,548

Applicant(s)

FLOWER, ROBERT

Examiner

Henry M. Johnson, III

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 4-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-30 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-25 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>030606</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

***Response to Arguments***

Applicant's arguments with respect to claims 1, 2 and 4-25 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitation "said fluorescing dye" in line 4. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 2, 4, 7, 8, 10, 11, 16-23 and 25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 00/47107 to Pang. Pang teaches a method for treating neovascularization of an eye where a feeder blood vessel is located using fluorescent imaging and confirming the locations (page 19, line 5), then using a laser to burn the feeder (page 20, line 30), confirming the feeder vessel is blocked by injecting indocyanine green (ICG) and confirming the vessel does not "fill" (page 21, line 2) and

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then using photodynamic therapy to treat the target where the photosensitizer has selectively been absorbed and irradiating the target with a frequency of the sensitizers wavelength. The confirmation of the blocking of the feeder vessel is interpreted as an alternative equivalent of confirming the exit rate of sensitizer from the target tissue as both serve the purpose of confirming the feeder is blocked. ICG is also disclosed as working as a photosensitizer (Page 21, lines 33-37) thus establishing its use as both a fluorescing agent and sensitizing agent. The ICG may be administered as a bolus (page 19, line 31). Pang teaches the time required for a dye to reach an eye is 10 to 25 seconds and then the image capture sequence begins, thus teaching a pre-defined time interval (page 15, line 35). The feeder identification uses the dye with illumination and image capture to positively locate the feeder vessel (page 14-16).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/47107 to Pang as applied to claim 4 above, and further in view of U.S. Patent 6,351,663 to Flower et al. Pang is discussed above, but does not teach a saline flush. Flower et al. teach the introduction of a liquid composition for CNV treatment as boluses comprising a fluorescent dye (Col. 4, line 17) and subsequent radiation. A saline flush may be administered flowing the bolus (Col. 4, line 58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a saline flush as taught by Flowers et al. in the method of Pang to control the levels of dye in the system

Claims 6, 9, 12-15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/47107 to Pang as applied to claim 1 above, and further in view of U.S. Patent 6,443,976 to Flower et al. Pang is discussed above, but does not teach administration of the composition over time periods, use of a liposome or confirmation of the sensitizer in the area to be treated. Flower et al. teach a method for treating a lesion, such as a CNV or tumor, in an animal. The methods contemplate treating such a lesion by subjecting the lesion to PDT, and subjecting a blood vessel that carries blood into the lesion to thermal photocoagulation to reduce the flow of blood through that vessel and into the lesion (Col. 2, lines 27-35). A fluorescent dye is used to obtain angiograms of the vasculature of interest to permit accurate targeting, while a radiation-absorbing dye is used in dye-enhanced photocoagulation effect treatment of feeder vessels (Col. 7, lines 1-5). This is the step of locating the feeder vessel. The PDT dyes are disclosed as hematoporphyrins, aminolevulinic acids, porphyrins, merocyanines, porphycenes, porfimer sodium, verteporfin, Photofrin II, PH-10, chlorins, zinc phthalocyanine, purpurins, pheophorbides, monoclonal antibody-dye conjugates of any of the foregoing dyes (abstract). The treatment step of thermal photocoagulation is preferably performed after the application of PDT when reperfusion of the CNV is detected, but the inventive methods are not limited to that sequence (Col. 6, lines 22-26). The methods and associated steps may be performed in any logical order (Col. 3, lines 36-37). The photocoagulation radiation-absorbing dyes are disclosed as fluorescein, rose bengal and indocyanine green (Col. 7, lines 31-35). Flower et al. teach a relationship between the type of photodynamic dye, the formulation, mode of administration, and dosage level, adjustment of these parameters to fit the particular combination to ensure delivery of an effective amount of the dye formulation to the targeted tissue is possible. (Col. 5, lines 20-26). This implies delivery over a set period of time based on the parameters. The delivery of dyes via liposomes is

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disclosed as being well known in the art (Col. 8, lines 11-16), and this is interpreted to include the various properties associated therewith. Flower et al. teach the radiation-absorbing dyes may also fluoresce, permitting the same dye to be used to obtain angiographic images of blood vessels, and treatment of vessels targeted as a result of the angiogram (Col. 7, lines 25-30), thus being used to confirm a target has "filled" with a treatment composition. It would have been obvious to one having ordinary skill in the art at the time the invention was made to look to the methods taught by Flower et al. for treating CNV and integrate portions to refine the invention of Pang to confirm agents within the target vessels prior to administration of the treatment radiation.

***Allowable Subject Matter***

Claims 26-30 are allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

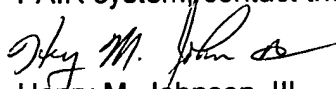
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Henry M. Johnson, III  
Primary Examiner  
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